

## REMARKS

The foregoing amendments and the following remarks are submitted in response to the communication dated April 20, 2005.

### *Status of the Claims*

Claims 15-22, 28-59, 61-67 and 69-83 are pending in the application. Claims 15-22 and 28-58, which are withdrawn from consideration, have been cancelled without prejudice. Claim 59 is also cancelled without prejudice. Claims 61-67 and 69-74 have been amended in order to more particularly point out and distinctly claim that which Applicants regard as the invention. Support for the amended claims can be found generally through Applicants' specification.

### *Claim Objections*

Claims 69-88 are objected to because the claims depend on a cancelled claim (claim 60). Applicants have above corrected the dependency of these objected claims, specifically of claims 69 through 74. The remaining objected claims are dependent from these now amended and properly corrected claims. Applicants submit that these amendments address the Examiner's objection.

### *The Specification Fully Describes the Claimed Invention*

The Examiner has rejected claim 63 (and dependent claims 69-88) under 35 U.S.C. 112, first paragraph, as failing to comply with the written-description requirement, asserting that the claims contain subject matter which was not described in the specification so as to convey that the inventors had possession of the claimed invention at the time of filing. The Examiner has maintained this lack of written description rejection, stating that although the specification has provided human OB and mouse OB proteins and that these proteins share 83% amino acid sequence identity, this does not provide a basis for a claim to a nucleic acid encoding a polypeptide that has 83% or greater amino acid sequence identity to the sequence of the human

or mouse OB (SEQ ID NOs: 2, 4, 5 or 6). The Examiner asserts that a genus of molecules is being claimed which were never described in the instant specification. Applicants disagree. The specification provide four sequences, two from mouse and two from human, and also provides, in Figure 4, a comparison of the mouse and human amino acid sequences lined up to one another with positions for differences and exemplary differences set out. Figure 4 provides 28 amino acid differences between the human and mouse sequences, out of 167 amino acids, giving 83% identity between the sequences. Thus, the specification describes exemplary molecules and sets out adequate teaching to the skilled artisan for making and testing additional such polypeptides with 83% or greater amino acid identity. Applicants also point out that the U.S. Patent Office has already issued a similar such claim in a copending and corresponding application, after considering the requirements for written description, particularly in U.S. Patent 5,935,810. Applicants additionally underscore that the instant claims do not relate to “any protein that varies by as much as 17% from the disclosed species” (see page 4 of the Office Action). To the contrary, Applicants claims necessitate that the protein be an OB polypeptide and be functionally active, capable of modulating body weight. Applicants also point out that at the time of the invention, Applicants identified the presence of a number of homologous sequences, hybridizing at moderate stringency conditions using labeled mouse OB nucleic acid as a probe, in rat, rabbit, vole, cat, cow, sheep, pig, chicken, eel, and drosophila. Applicants assert that, given all of the above, the inventors at the time the application was filed, had possession of the claimed genus.

In view of the foregoing remarks, Applicants submit that the Examiner’s rejection under 35 U.S.C. 112, first paragraph, may properly be withdrawn.

### ***Particularity and Distinctiveness of the Claims***

The Examiner has rejected claims 59 and 69-88 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter applicant regards as the invention.

The Examiner rejects Claim 59 in the language “moderate stringency conditions”, asserting that there is no one set of conditions provided in the Specification for what is intended

to be “moderate stringency conditions” and, based on the fact that results will differ based on what values are used for the different variables involved in hybridization, the metes and bounds of the claim cannot be determined. Applicants respectfully disagree and assert that the metes and bounds of moderate stringency hybridization conditions are clear and can be readily determined and practiced by the skilled artisan. Applicants, however, have above cancelled claim 59, without prejudice, in as much as the nucleic acids set out in claim 59 are claimed in copending applications, including now issued U.S. Patent(s).

Claims 61-67 are rejected as indefinite. In particular, the Examiner remarks that there is no indication of what is “capable of modulating body weight” – the polypeptide or the nucleic acid molecule. The Examiner further states that there is likewise no indication whether the polypeptide or the nucleic acid has “one or more polymers attached thereto”. Applicants have above amended claims 61-67 to clarify the language and address this rejection and submit that the claims as now presented are clear. As provided in the claims, the OB polypeptide is capable of modulating body weight and the OB polypeptide has polymers attached to it.

Further, the Examiner remarks at page 7 of the Office Action that the claims are not enabled for the full breadth of “polymers”. The Examiner points out that, for example, polyethylene glycol, a common polymer which is attached to polypeptides to increase half-life, cannot be encoded by a nucleic acid. Applicants have above amended the claims to clarify, as noted above, that the nucleic acid encodes OB polypeptide and also encodes a polymer attached to said OB polypeptide. It would be obvious to the skilled artisan that only certain types of polymers, including polyamino acids, can be nucleic acid encoded. Applicants assert that the claims as presented are definite and clearly directed to nucleic acid encoded polymers.

In view of the foregoing amendments and remarks, Applicants submit that the Examiner's above noted rejections under 35 U.S.C. 112, second paragraph, may be properly withdrawn.

### ***The Double Patenting Rejection***

The Examiner has provisionally rejected claims 59, 61-67 and 69-88 under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 5,935,801 and claims 1-21 of U.S. Patent No. 6,309,853 (“the ‘853 Patent”). With regard to the double patenting rejection over 5,935,801, Applicants believe the Examiner

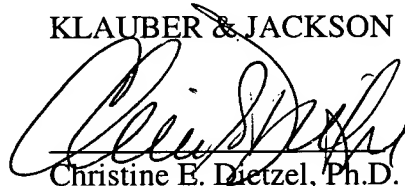
has provided an inadvertently incorrect patent number, and intends to refer to U.S. Patent No. 5,935,810 ("the '810 Patent"), which issued from an originally copending application. The '810 Patent and the '853 Patent claim nucleic acids encoding OB polypeptides. The Examiner asserts that the proteins, as encoded by the claimed nucleic acids, of the '810 Patent and the '853 Patent use comprising language and therefore conceivably include additional amino acids such as polyamino acids. Applicants point out that claim 59 has above been cancelled. Applicants submit that the instant claims are distinct from the claims of the '810 Patent and the '853 Patent and are not obvious or unpatentable in view of these issued patents. Instead, the instant claims are directed to different and distinct nucleic acid subject matter from the claims in either the '810 Patent and the '853 Patent. In particular, each and all of the instant claims include and claim nucleic acids encoding both OB polypeptide(s) and also encoding one or more polymers attached to said OB polypeptide(s). In certain of the claims, a further limitation adding optionally a pharmaceutical carrier is claimed. These claims represent a distinct invention, with a different inventive entity and are useful for additional purposes, having a polymer attached thereto. Accordingly, Applicants submit that the instant claims obviate the double patenting rejections and are patentably distinct, not having been specifically or particularly claimed in either the '810 Patent or the '853 Patent.

CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks in the file history of the instant Application. The Claims as amended are believed to be in condition for allowance, and reconsideration and withdrawal of all of the outstanding rejections is therefore believed in order. Should the Examiner feel that further issues remain upon a review of this response, she is invited to call the undersigned at the number listed below to effect their resolution. Early and favorable action on the claims is earnestly solicited.

Respectfully submitted,

KLAUBER & JACKSON

A handwritten signature in black ink, appearing to read 'Christine E. Dietzel', is written over a horizontal line.

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